OCT - 5 2001

SECTION 15: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

15.1 SUBMITTER INFORMATION

a. Company Name:	Measurement Specialties, Inc.
b. Company Address:	80 Little Falls Road Fairfield, NJ 07004
c. Company Phone: Company Facsimile:	(973) 808-1819 (973) 808-1787
d. Contact Person:	Dr. Steven Petrucelli Chief Technology Officer
e. Date Summary Prepared:	July 6, 2001

15.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Measurement Specialties, Inc. Body Composition Analyzer Models A and B
b. Classification Name:	Body Composition Analyzer 21 CFR 870.2770 74 MNW

15.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Tanita Corporation Of America	Body Fat Analyzer	K930599	11/01/1994
Omron Healthcare	Body Composition Analyzer	K963575	06/13/1997

15.4 DEVICE DESCRIPTION

The Measurement Specialties, Inc., body composition analyzer is a stand-on patient scale used for the personal monitoring of body weight and body fat composition. The body composition analyzer is programmable for two separate individuals and uses bioelectric impedance technology for the estimation of percent body fat. The body composition analyzer is ideal for in-home use for personal monitoring of weight and body fat.

15.5 SUBSTANTIAL EQUIVALENCE

The body composition analyzer is substantially equivalent to the Tanita Corporation of America Body Fat Analyzer and the Omron Healthcare Body Composition Analyzer.

The fundamental technical characteristics and indications for use of the Body Composition Analyzer are similar to those of the predicate devices. The Measurement Specialties body composition analyzer and the predicate devices use bioelectric impedance for the estimation of percent body fat. The body composition analyzer and the predicate devices are indicated for personal home use.

15.6 INDICATIONS FOR USE

The Body Composition Analyzer is intended for use in the estimation of percent body fat and body weight.

15.7 TECHNOLOGICAL CHARACTERISTICS

The Body Composition Analyzer is a programmable patient stand-on scale that measures patient weight and percent body fat. The device utilizes the technology

of bioelectric impedance to determine the transmission speed of a low level electrical current through the patient. The device software utilizes the impedance data, patient weight, gender, age, and height data to calculate the patient percent body fat.

A comparison of the technological characteristics and performance testing of the Body Composition Analyzer to those of the predicate devices has been provided in this submission.

15.8 PERFORMANCE DATA

Performance testing was conducted on the Body Composition Analyzer for functionality, reliability, repeatability and reproducibility. All results were shown to be acceptable. In addition, comparison testing was performed using the Body Composition Analyzer and the predicate devices. Results of the testing showed that the Body Composition Analyzer was equivalent in performance to those of the predicate devices. The Body Composition Analyzer was shown to perform as intended.

15.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2001

Measurement Specialties, Inc.
c/o Ms. Carol Patterson
President
Patterson Consulting Group, Inc.
21911 Erie Lane
LAKE FOREST CA 92630

Re: K010706
Trade/Device Name: Measurement Specialties, Inc. Body Composition Analyzer Models A and B
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: July 6, 2001
Received: July 9, 2001

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K010706

Device Name: Measurement Specialties, Inc. Body Composition Analyzer - Model A and Model B

Indications for Use: The Body Composition Analyzer is intended for the estimation of percent body fat and body weight.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010706

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)